OCCUPATIONAL SAFETY AND HEALTH RESEARCH

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National Institute for Occupational Safety and Health
National Cancer Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute on Deafness and Other Communication Disorders
National Institute of Environmental Health Sciences

THIS PROGRAM ANNOUNCEMENT (PA) USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD PPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS PA.

PURPOSE

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) invite grant applications for research related to the priority areas identified in the National Occupational Research Agenda (NORA) that are described in the RESEARCH OBJECTIVES section.

The overall purpose of this grants program is to develop knowledge that can be used in preventing occupational diseases and injuries and to better understand their underlying pathophysiology. This purpose is shared by several components of the Public Health Service within the CDC and the NIH. Within CDC, the National Institute for Occupational Safety and Health (NIOSH) is the only Federal Institute responsible for conducting research and making recommendations for the prevention of work-related illnesses and injuries; however, there are other Federal components that contribute significantly to the research base for understanding the causes of occupational illnesses and injuries. Broad statements of interest for the sponsors of

this program announcement are given below, and more information about their individual interests may be found on their respective internet sites.

NIOSH supports research to identify and investigate the relationships between hazardous working conditions and associated occupational diseases and injuries; to develop more sensitive means of evaluating hazards at work sites, as well as methods for measuring early markers of adverse health effects and injuries; to develop new protective equipment, engineering control technology, and work practices to reduce the risks of occupational hazards; and to evaluate the technical feasibility or application of a new or improved occupational safety and health procedure, method, technique, or system.

The National Cancer Institute (NCI) supports training and research in the basic, population-based, and clinical sciences related to the causes, detection, prevention, diagnosis, prognosis, and treatment of cancer. Basic and applied research is also supported for advancing cancer control strategies by investigating factors (e.g., exogenous exposures, genetic susceptibility, behavioral and lifestyle patterns) influencing cancer risk in individuals and population subgroups and by application of surveillance activities and dissemination of public health information.

The National Heart, Lung and Blood Institute (NHLBI) supports an integrated and coordinated program of basic research, clinical investigations and trials, observational studies, and demonstration and education projects. Research is related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The NHLBI plans and directs research in the development and evaluation of interventions and devices related to prevention, treatment, and rehabilitation of patients suffering from such diseases and disorders. It also supports research on clinical use of blood and all aspects of the management of blood resources.

The National Institute on Aging (NIA) supports research on basic mechanisms involved in aging processes and the onset of age-related disease; social and behavioral research on aging processes and the place of older people in society; the structure and function of the aging nervous system and the behavioral manifestations of the aging brain; and topics related to the causes, prevention, and treatment of older people's health problems.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) supports basic and applied research on the causes, consequences, treatment and prevention of alcohol-related problems including research into the effects of alcohol on the human mind and body, prevention and

treatment of alcohol abuse and alcoholism among general and specific populations, the epidemiology of alcoholism and alcohol-related problems, and health services research.

The National Institute of Allergy and Infectious Diseases (NIAID) conducts, fosters, and supports research and research training programs directed at finding the cause of and improved methods for diagnosing, treating, and preventing immunologic and infectious diseases which significantly affect public health.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports basic, clinical, and epidemiologic research and research training and disseminates information on many forms of arthritis and diseases of the musculoskeletal system and the skin, including (1) the normal structure and function of joints, muscles, bones, and skin and (2) clinical research in the fields of rheumatology, orthopedics, dermatology, metabolic bone diseases, heritable disorders of bone and cartilage, inherited and inflammatory muscle diseases, and sports- and rehabilitation medicine.

The National Institute on Deafness and Other Communication Disorders (NIDCD) supports biomedical and behavioral research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech and language; disease prevention and health promotion; special biomedical and behavioral problems associated with people who have communication impairments or disorders; and creation of devices which substitute for lost and impaired sensory and communication function.

The National Institute of Environmental Health Sciences (NIEHS) supports research to reduce the burden of human illness and dysfunction from exposure to physical and chemical agents in the environment by understanding the interactions between environmental exposures, individual susceptibility and time.

HEALTHY PEOPLE 2000

CDC and NIH are committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. This program announcement is related to the priority areas of occupational safety and health and unintentional injuries. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0 or Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800, or at http://www.crisny.org/health/us/health7.html

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

MECHANISM OF SUPPORT

This PA will use the research project grants (R01) mechanism. A research project grant application should be designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for dealing with problems. These studies may generate information that is readily available to solve problems or contribute to a better understanding of the causes of work-related diseases and injuries.

Grants are funded for 12-month budget periods in project periods up to five years. Continuation awards within the project period are made on the basis of satisfactory progress and on the availability of funds.

Specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts being examined by the NIH. Complete and detailed instructions and information on Modular Grant applications can be found at http://grants.nih.gov/grants/funding/modular/modular.htm

RESEARCH OBJECTIVES

In today's society, Americans are working more hours than ever before. The workplace environment profoundly affects health; each of us, simply by going to work each day, may face hazards that threaten our health and safety. Risking one's life or health should never be

considered merely part of the job. In 1970, Congress passed the Occupational Safety and Health Act to ensure Americans the right to "safe and healthful working conditions," yet workplace hazards continue to inflict a tremendous toll in both human and economic costs. Employers reported 5.8 million work injuries in 1996 and 439,000 cases of occupational illness. An average of 16 American workers die each day from injuries on the job. Moreover, even the most conservative estimates find that about 137 additional workers die each day from workplace diseases. Additionally, in 1996 occupational injuries and deaths cost $121 billion in wages and lost productivity, administrative expenses, health care and other costs. This does not include the cost of occupational disease. These occupational injuries and diseases create needless human suffering, a tremendous burden upon health care resources, and an enormous drain on U.S. productivity.

In 1996, the National Institute for Occupational Safety & Health (NIOSH) and its partners in the public and private sectors developed the National Occupational Research Agenda (NORA) to provide a framework to guide occupational safety and health research into the next decade, not only for NIOSH, but also for the entire occupational safety and health community. Approximately 500 organizations and individuals outside NIOSH provided input into the development of the National Occupational Research Agenda (NORA). This attempt to guide and coordinate research nationally is responsive to a broadly perceived need to address systematically those topics that are most pressing and most likely to yield gains to the worker and the nation. Fiscal constraints on occupational safety and health research are increasing, making even more compelling the need for a coordinated and focused research agenda.

Potential applicants may obtain a copy of the "National Occupational Research Agenda" (HHS, CDC, NIOSH Publication No.96-115) from the National Institute for Occupational Safety and Health, telephone (800) 356-4674. It is also available on the internet at "http://www.cdc.gov/niosh/nora.html".

The agenda identifies 21 research priorities and reflects an attempt to consider both current and emerging needs. The priority areas are not ranked; each is considered to be of equal importance. The NORA priority research areas are grouped into three categories: Disease and Injury, Work Environment and Workforce, and Research Tools and Approaches.

Applications responding to this announcement will be reviewed for their responsiveness to the following program interests and their potential for developing knowledge that can be used in preventing occupational diseases and injuries. Applicants should provide a statement about which NORA area is being addressed and a rationale for how the proposal will contribute to the

specified priority area (this information should be placed in the "Background and Significance" section of the "Research Plan" of the application). Assignment of applications to sponsoring Institutes will be made on the basis of matching the research topics with the appropriate programmatic interests. Applicants are encouraged to contact individuals listed under INQUIRIES if they wish to discuss the relevance of their research ideas.

NORA Priority Research Areas are:

Disease and Injury

1. Allergic and Irritant Dermatitis
2. Asthma and Chronic Obstructive Pulmonary Disease
3. Fertility and Pregnancy Abnormalities
4. Hearing Loss
5. Infectious Diseases
6. Low Back Disorders
7. Musculoskeletal Disorders of the Upper Extremities
8. Traumatic Injuries

Work Environment and Workforce

9. Emerging Technologies
10. Indoor Environment
11. Mixed Exposures
12. Organization of Work
13. Special Populations at Risk

Research Tools and Approaches

14. Cancer Research Methods
15. Control Technology and Personal Protective Equipment
16. Exposure Assessment Methods
17. Health Services Research
18. Intervention Effectiveness Research
19. Risk Assessment Methods
20. Social and Economic Consequences of Workplace Illness and Injury
21. Surveillance Research Methods

Potential applicants with questions concerning the acceptability of their proposed work are strongly encouraged to seek programmatic technical assistance from the contact listed in this announcement under the section "INQUIRIES."

SPECIAL REQUIREMENTS

Human Subjects

If a project involves research on human subjects, assurance (in accordance with Department of Health and Human Services Regulations, 45 CFR Part 46) of the protection of human subjects is required. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. Unless the grantee holds a Multiple Project Assurance, a Single Project Assurance is required, as well as an assurance for each subcontractor or cooperating institution that has immediate responsibility for human subjects. The Office for Protection from Research Risks (OPRR) at the National Institutes of Health (NIH) negotiates assurances for all activities involving human subjects that are supported by the Department of Health and Human Services.

It is the policy of the CDC and the NIH that women and members of minority groups and their sub-populations must be included in all supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994. It is also available at: http://www.nih.gov/grants/guide/1994/94.03.18/notice-nih-guideline008.html

Animal Subjects Requirements

If the proposed project involves research on animal subjects, compliance with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions" is required. An applicant

(as well as each subcontractor or cooperating institution that has immediate responsibility for animal subjects) proposing to use vertebrate animals in CDC and NIH supported activities must file (or have on file) the Animal Welfare Assurance with the Office for the Protection from Research Risks (OPRR) at the National Institutes of Health. The applicant must provide in the application the assurance of compliance number and evidence of review and approval (including the date of the most recent approval) by the Institutional Care and Use Committee (IACUC).

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the CDC and NIH to ensure that individuals of both sexes and the various racial and ethnic groups will be included in supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://www.nih.gov/grants/guide/notice-files/not98-024.html.

LOBBYING RESTRICTIONS

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of PHS appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev.4/98) and will be accepted at the standard application receipt dates indicated in the application kit. These forms are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: grantsinfo@nih.gov. Application kits are also available at: http://www.nih.gov/grants/forms.htm

Applicants planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended/revised version of the preceding grant application types requesting $500,000 or more in direct costs for any year are advised to contact the Institute or Center (IC) program staff before submitting the application, i.e., as plans for the study are being developed. The applicant must obtain agreement from the IC staff that the IC will accept the application for consideration for award. Finally, the applicant must identify, in a cover letter sent with the application, the staff member and Institute or Center who agreed to accept assignment of the application. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 at http://grants.nih.gov/grants/guide/notice-files/not98-030.html.

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff. The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below.

BUDGET INSTRUCTIONS

Modular Grant applications will request direct costs in $25,000 modules, up to a total direct cost request of $250,000 per year. (Applications that request more than $250,000 direct costs in any year must follow the traditional PHS 398 application instructions.) The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.

o Under Personnel, List key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should

use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.
- List selected peer-reviewed publications, with full citations;

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

Applicants not conforming to these guidelines will be considered unresponsive and will be returned without further review.

The title and number of the program announcement must be typed on line 2 of the face page of the application form, and the YES box must be marked. Submit a signed, typewritten original of the application, including the Checklist, and five signed, photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures will evaluate applications for scientific and technical merit. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2. Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5. Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, all applications will be reviewed with respect to the following:

o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The reasonableness of the proposed budget and duration in relation to the proposed research.

o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review, availability of funds, and institutional program priority.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

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Direct inquiries regarding grants management matters to:

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2920 Brandywine Road, MS-E13

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos.93.262 NIOSH; 93.393 NCI; 93.837, 93.838, and 93.839 NHLBI; 93.866 NIA; 93.273 NIAAA; 93.855, 93.856 NIAID; 93.846 NIAMS; 93.173 NIDCD; and 93.113 and 93.115 NIEHS. This program is authorized under the Public Health Service Act, as amended, Section 301(a) [42 U.S.C. 241(a)], and the Occupational Safety and Health Act of 1970, Section 20(a) [29 U.S.C. 669(a)]. The applicable program regulation is 42 CFR Part 52.

The CDC and NIH strongly encourage all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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